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| 10/575,690      | 08/23/2006  | Torsten Brandenburger | 3632.1003-000       | 3600             |

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| EXAMINER |
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DEAK, LESLIE R

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| ART UNIT | PAPER NUMBER |
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3761

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10/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/575,690 | <b>Applicant(s)</b><br>BRANDENBURGER ET AL. |  |
|                              | <b>Examiner</b><br>LESLIE R. DEAK    | <b>Art Unit</b><br>3761                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-31.33-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-31.33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 100 30 474 C1 to Rahimy in view of US 5,100,394 to Dudar et al.

In the specification and figures, Rahimy discloses the apparatus substantially as claimed by Applicant. With regard to claims 1 and 34, Rahimy discloses a connector with a connection part 2 with a channel-shaped recess 8 in which a self-sealing membrane 4 is arranged, wherein the recess has openings at either end (see FIG 1). The connector further comprises a break-off part 6 that closes the recess and is connected to the connection part 2 above the connection-side opening. The connection part has an internal cone above the membrane and is connected to a package for medical liquids (see FIGS 1, 6).

Rahimy fails to disclose that the membrane comprises a slit to receive a syringe. However, Dudar discloses a connector with a channel and a membrane 52 comprising a

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resealable opening or slit 66 that allows for repeated access with a blunt cannula, preventing accidental needle sticks (see Dudar FIG 3 and accompanying text). Dudar discloses that when a blunt cannula enters the membrane, it separates the slit, allowing the membrane to separate without the cannula penetrating the surface of the septum. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a slit as disclosed by Dudar to the connection apparatus disclosed by Rahimy in order to allow repeated resealable access by a blunt cannula, as taught by Dudar.

With regard to claims 19 and 20, Rahimy illustrates that the connection part 6 comprises a female Luer connector thread (unlabeled, flange under weakened zone 7) and an internal cone.

With regard to claim 21, Rahimy illustrates that break-off part 8 is connected to the connection part 6 via a rupture zone at 7.

With regard to claims 22 and 23, Rahimy illustrates that the connection part has an upper section 2 and a lower section 3, wherein the pieces are fixed in a snap-in fashion by flange 1 (see FIG 1), wherein the membrane is clamped between the upper and lower sections.

With regard to claims 24-26, the Rahimy membrane 4 comprises a lower annular portion 11 and with an intermediate pieces that leads to an upper plate-shaped portion with a mould-shaped recess 5, wherein the annular portion is clamped between the upper and lower sections of the connection parts 2, 3 (see FIG 1).

With regard to claims 27 and 28, the Rahimy connection part comprises two-inwardly-facing shoulders, upon which the annular portion and plate-shaped portion of the membrane rest (see FIG 1).

With regard to claims 29 and 30, Applicant is claiming the functional relationship between the membrane and the connection parts. It is the position of the Examiner that the apparatus suggested by the combination of Rahimy and Dudar is capable of being assembled in the manner claimed by Applicant, thereby suggesting the limitations of the claims.

With regard to claim 31, Rahimy illustrates that the annular portion of the membrane has a smaller diameter than the inner diameter of the channel-shaped recess in the connection part (see FIG 1).

With regard to claim 33, Rahimy illustrates break-off portion 6 as a flat grip, And further illustrates that the connector may be connected to bag 19 (see FIG 3).

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

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by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 18-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/514,817. Although the conflicting claims are not identical, they are not patentably distinct from each other because each claims a tubular connection part, a break-off seal, and a septum with the same claimed shape.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

6. Applicant's arguments filed 22 July 2009 with regard to the 35 U.S.C. §112 rejection of claim 30 are persuasive, and the rejection has been withdrawn.

7. Applicant's arguments filed 22 July 2009 with regard to the art rejections over the pending claims have been fully considered but they are not persuasive.

8. Applicant argues that the Rahimy reference shows a connection piece, but that the internal cone is within the break-off part, and not the connection piece, as set forth in the claims. However, in the figures provided by Applicant, cone 14 is illustrated as being a part of the break-off portion 17 (see FIG 2 wherein cone 14 is illustrated as being above line 16, which is the rupture zone disclosed by Applicant). Accordingly, the cone 14 as illustrated and disclosed by Applicant is part of the break-off portion of the connector. The Rahimy reference corresponds to the limitations disclosed by Applicant. Furthermore, the Rahimy reference illustrates a divot in the membrane at 5 that dips below the upper rim of connection part 7. This divot may be broadly interpreted to correspond to the "internal cone" claimed by Applicant.

9. Applicant further argues that neither reference discloses a connection piece and membrane that is merely separated, but not penetrated, by an insertion member. However, both Dudar and Rahimy teach pre-slit membranes that are entirely capable of resealing after insertion of a cannula or syringe (see opening 5 disclosed by Rahimy, pre-slit membrane 134a disclosed by Dudar). Since both references disclose a membrane that may operate as claimed by Applicant, the instantly claimed invention is unpatentable over the prior art.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
7 October 2009